IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. FLAWLESS BEAUTY LLC, and RDG IMPORTS LLC, limited liability companies, and JACK H. GINDI, and SUSANA B. BOLECHE, individuals, Defendants.	)	Case No. 17-7091 (PGS)

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Flawless Beauty LLC ("Flawless") and RDG Imports LLC ("RDG"), limited liability companies, and Jack H. Gindi, and Susana B. Boleche, individuals (collectively, "Defendants"), and Defendants solely for the purposes of settlement of this case, and without admitting or denying the allegations in the Complaint, having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action pursuant to 21 U.S.C. § 332 and its inherent equitable authority, and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), 353(b)(1), and 353(b)(4).

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of drugs that they hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), 353(b)(1), and 353(b)(4).

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, affiliates, and "doing business as" entities) (collectively, "Associated Persons"), who receive notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly importing, receiving, manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any articles of drug, unless and until:

(A) An approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. 355 §§ (a), (j), or (i) is in effect for such drugs; or

(B) Defendants retain, at Defendants' expense, an independent person or persons (the "Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, and experience, is qualified to review the claims Defendants make for each of their drug products on all labels, labeling, promotional materials, and websites owned, controlled by, or related to Defendants, including, but not limited to: www.flawlessbeautyandskin.com; www.relumins.com; Defendants' Google+ page; Defendants' Facebook page; and Defendants' postings on eBay, Amazon, and other online marketplace websites (collectively, "Defendants' websites");

(1) Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the Expert as soon as they retain the Expert;

(2) The Expert shall perform a comprehensive review of Defendant's compliance with the Act, its implementing regulations, and this Decree; and

(3) Defendants and/or the Expert shall remove all claims that cause Defendants' products to be unapproved new drugs from all labels, labeling, including promotional materials, Defendants' websites, and any other sources owned or controlled by or related to Defendants and/or their articles of drug; and

(C) The Expert certifies to FDA in a written report a list of the materials he or she has reviewed, including, but not limited to, all labels, labeling, including promotional

materials and websites, and any other sources owned or controlled by or related to Defendants and/or their articles of drug, and whether Defendants are operating in compliance with the Act, its implementing regulations, and this Decree;

(1) The report shall include copies of all materials reviewed by the Expert; and

(2) The Expert shall submit the report concurrently to Defendants and FDA no later than ten (10) calendar days after completing this review; and

(D) Should the Expert identify any deficiencies in his or her report described in Paragraph 6(C):

(1) Defendants shall report to FDA and the Expert in writing the actions they have taken to correct all such deficiencies; and

(2) The Expert shall certify in writing to FDA, based upon the Expert's further review and/or inspection(s), whether Defendants have omitted all claims from each of their product labels, labeling, including promotional materials, Defendants' websites, and in any other source owned or controlled by or related to Defendants and/or their articles of drug, which cause Defendants' products to be drugs under the Act; and

(E) Defendants shall provide FDA any additional information it requests after FDA's review of the Expert's report; and

(F) FDA representatives may also inspect Defendants' facility to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Decree. The cost of FDA's inspections under this Subparagraph shall be borne by Defendants at the

rates specified in Paragraph 15. Such inspection, if any, will be initiated within thirty (30) business days after receiving the Expert report under Paragraph 6(C), Defendants' corrective actions (if any) under Paragraph 6(D), and any materials requested by the agency under Paragraph 6(E);

(G) FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Subparagraphs 6(B) – (F).

7. Within twenty (20) calendar days of entry of this Decree, Defendants shall recall and destroy, under FDA supervision and to FDA's satisfaction, LingZhi Plus and any ampule or lyophilized vial, including those sold as part of "whitening kits" or "kits" that Defendants imported, manufactured, prepared, processed, packaged, labeled, held and/or distributed before entry of this Decree, including, but not limited to: Relumins Vitamin C; Relumins Advanced Glutathione, including "whitening kits;" Relumins Solvent for Glutathione; Relumins Reduced Glutathione Powder; TP Drug Laboratories Vitamin C; Tatiomax Glutathione; Tatiomax Glutathione + Hydrolyzed Collagen, including "whitening kits;" Tatiomax Reduced Glutathione; Tatiomax vials and powders; Saluta Glutathione; Saluta Reduced Glutathione; "Sterile" Water for injection; Laroscorbine Platinum Vitamin C with collagen, including all "kits;" Tationil Glutathione; Laennec Human Placenta Whitening; Reiki Glutathione Whitening; and TAD Glutathione. Defendants shall, under FDA supervision and to FDA's satisfaction, notify all affected consumers of the recall. Defendants shall not dispose of any drugs in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory in which the drugs are disposed. Defendants shall bear the cost of the recall, destruction notification, and FDA supervision. The cost of FDA's participation and supervision under this Paragraph shall be borne by Defendants at the rates specified in Paragraph 15.

8. After Defendants have complied with Subparagraphs 6(B) – (F), and FDA has notified Defendants in writing pursuant to Subparagraph 6(G), Defendants shall notify FDA on the first day of each month, at the address specified in Paragraph 19 of this Order, of their intent, if any, to market any FDA-regulated product(s) that were not included in the Expert report submitted under Paragraph 6(C) ("New Products"). Such notification shall include the name of each New Product and all proposed labels, labeling, and promotional materials for each New Product. Defendants shall ensure that all such activity shall be in full compliance with this Decree, the FDCA, and its implementing regulations.

9. After Defendants have complied with Subparagraphs 6(B) – (F), and FDA has notified Defendants in writing pursuant to Subparagraph 6(G), Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' drug products and their labeling, including Defendants' websites and promotional materials, and any other source owned or controlled by or related to Defendants and/or their articles of drug, not less than once every six (6) months for a period of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement with Defendants) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in Subparagraph 6(B). Additionally:

(A) Defendants shall notify FDA in writing of the identity and qualifications of the Auditor as soon as they retain the Auditor;

(B) At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' drug products and their labeling, including Defendants' websites, product labeling, and promotional

materials, and any other source owned or controlled by or related to Defendants and/or their articles of drug, are in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations");

(C) Each Audit Report shall also contain a written certification that the Auditor:

(1) has personally reviewed all of Defendants' drug products and their labeling, including Defendants' websites and promotional materials, and any other source owned or controlled by or related to Defendants and/or their articles of drug; and

(2) has personally certified whether all of Defendants' drug products and their labeling, including Defendants' promotional materials and websites, and any other source owned or controlled by or related to Defendants and/or their articles of drug, comply with the requirements of the Act, its implementing regulations, and this Decree;

(D) As part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations;

(E) The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) calendar days after the date the audit inspections are completed;

(F) If any Audit Reports identify any deviations from the Act, applicable regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew;

(G) Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request; and

(H) If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within twenty (20) calendar days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than twenty (20) calendar days, Defendants shall, within ten (10) calendar days after receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. The Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Correction Schedule. Within ten (10) calendar days after Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observations. Within two (2) calendar days after beginning that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

10. Upon entry of this Decree, Defendants and all of their Associated Persons are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

(A) Violates 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product that is a new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval under 21 U.S.C. § 355(i);

(B) Violates 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), 353(b)(1), and 353(b)(4);

(C) Violates 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), 353(b)(1), and 353(b)(4); and/or

(D) Fails to implement and continuously maintain the requirements of this Decree.

11. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, a report submitted by Defendants, the Expert, the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

(A) Cease importing, receiving, manufacturing, preparing, processing, packing, labeling, holding, selling, and/or distributing all drug products;

(B) Recall and/or destroy, at Defendants' expense, any drug products that are unapproved, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

(C) Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

(D) Submit additional reports or information to FDA as requested;

(E) Issue a safety alert; and/or

(F) Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of Paragraph 11 shall be apart from, and in addition to, all other remedies available to FDA.

12. Upon receipt of any order issued by FDA pursuant to Paragraph 11, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 11 shall be borne by Defendants at the rates specified in Paragraph 15.

13. FDA shall be permitted, without prior notice and when FDA deems necessary, to make inspections of the Defendants' place(s) of business, and, without prior notice, take any

other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and FDA regulations. During inspections, FDA shall be permitted to have immediate access to buildings, company-owned vehicles, equipment, products, labeling, and other materials therein; take photographs and make video recordings; take samples of Defendants' products, containers, packaging material, labeling, and other materials; and examine and copy all records relating to the importing, receiving, manufacturing, preparing, processing, packing, labeling, holding, and/or distributing all drugs. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

14. Defendants shall promptly provide any information or records to FDA upon request regarding the importing, receiving, manufacturing, preparing, processing, packing, labeling, holding, and/or distribution of Defendants' products. Defendants shall submit, within ten (10) calendar days, a copy of the materials FDA requests, including, but not limited to, labels, labeling, promotional materials, downloaded copies of any of Defendants' websites, and/or any other sources owned or controlled by or related to Defendants and/or their articles of drug (on CD-ROM), to FDA at the address specified in Paragraph 19.

15. Defendants shall pay all costs of all FDA inspections, investigations, analyses, examinations, sampling, reviews, document preparation, testing, travel, and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, at the standard rates prevailing at the time costs are incurred, and Defendants shall make payment in full to the United States within twenty (20) calendar days of receiving written notification from FDA of such costs. For the purposes of this Decree, inspections include, but are not limited

to, FDA review and analysis of Defendants' product labels, labeling, promotional materials, Defendants' websites, and any other sources owned or controlled by or related to Defendants or their articles of drug. As of the date of this Decree, these rates are: $93.26 per hour and fraction thereof per representative for inspection or investigative work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 per mile for travel by motor vehicle; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative and for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

16. Defendants shall provide notice of this Decree in the following manner:

(A) Within ten (10) calendar days after entry of this Decree, Defendants shall:

(1) Provide a copy of this Decree, personally or, when necessary, by certified mail (return receipt requested) to all Associated Persons;

(2) Post a copy of this Decree both in a conspicuous location in a common area at Defendants' facility and on Defendants' websites, and ensure the Decree remains posted for as long as the Decree remains in effect;

(3) Hold a general meeting or series of smaller meetings for all employees, at which Defendants shall describe the terms and obligations of this Decree; and

(4) Provide to FDA a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to Subparagraph 16(A)(3).

(B) Within twenty (20) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of their compliance with Subparagraph 16(A).

17. In the event that any of the Defendants becomes associated with additional Associated Persons at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Persons;

(A) Each time Defendants become associated with an additional Associated Person, they shall, within ten (10) calendar days, provide FDA an affidavit stating the fact and manner of their compliance with Paragraph 17, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this Paragraph and the manner of such notification; and

(B) Within ten (10) calendar days of receiving a request from FDA for any information or documentation FDA deems necessary to evaluate compliance with Paragraph 17, Defendants shall provide such information or documentation to FDA.

18. Defendants shall notify FDA in writing at the address specified in Paragraph 19, at least fifteen (15) calendar days before any change in ownership, character, or name of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in the organizational structure of Flawless or RDG or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree;

(A) Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment; and

(B) Defendants shall furnish FDA with an affidavit stating the fact and manner of their compliance with Paragraph 18 no later than ten (10) calendar days before such assignment or change in ownership.

19. All notifications, certifications, reports, correspondence, and other communications to FDA required under this Decree shall be addressed to the District Director, United States Food and Drug Administration, Office of Pharmaceutical Quality Operations, Division 1, 10 Waterview Boulevard, Parsippany, 3rd Floor, New Jersey 07054, and shall prominently reference this Consent Decree, the case name, and civil action number. Defendants may also send courtesy copies of any notifications, certifications, reports, correspondence, and other communications to FDA required under this Decree to District Director, United States Food and Drug Administration, Office of Pharmaceutical Quality Operations, Division 1, at orapharm1opdiv1mgmt@fda.hhs.gov.

20. If Defendants have maintained a state of continuous compliance with the law and this Decree for at least 60 months after receiving FDA's notification under Paragraph 6(G), Defendants may petition the Court for relief from this Decree, and the Government will not oppose the petition.

21. Under no circumstances shall FDA's silence be construed as a substitute for written notification.

22. Should Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations, they shall pay to the United States of America Ten Thousand Dollars ($10,000.00) in liquidated damages for each violation of this Decree, the Act, and/or its

implementing regulations; an additional Three Thousand Dollars ($3,000.00) in liquidated damages per day, per violation, for each violation of this Decree, the Act, and/or its implementing regulations; and an amount equal to twice the retail value of any drugs distributed in violation of the Act, its implementing regulations, and/or this Decree. Defendants understand and agree that the liquidated damages specified in Paragraph 22 are not punitive in nature and their imposition does not in any way limit Plaintiff's ability to seek, and the Court to impose, additional civil or criminal penalties based on conduct that may also be the basis for payment of liquidated damages.

23. Should Plaintiff bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and court costs or any other fees relating to such contempt proceedings.

24. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, if challenged, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

25. This Decree resolves only the claims in this statutory injunction action brought under 21 U.S.C. § 332(a) as set forth in the Complaint. Defendants specifically state and agree that entry of this Decree does not preclude any other civil, criminal, or administrative claims that the government may have or may bring in the future against any of the Defendants herein in

connection with, or relating to, any of the Defendants' activities involving FDA-regulated products, including the conduct alleged in the Complaint filed with this Decree.

26. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED this 25 day of September, 2017.

Peter G. Sheridan
United States District Judge

We hereby consent to the entry of the forgoing Decree:

FOR DEFENDANTS

JACK H. GINDI, individually, and on behalf of FLAWLESS BEAUTY LLC and RDG IMPORTS LLC

SUSANA B. BOLECHE, individually, and on behalf of FLAWLESS BEAUTY LLC

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